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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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10/629,123

07/28/2003

David Pickar

26811-010 UTIL

5912

7590

07/27/2006

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EXAMINER

SOROUGH, LAYLA

ART UNIT

PAPER NUMBER

1617

DATE MAILED: 07/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------------------|--------------------------------------|--|
| Office Action Summary | Application No. 10/629,123 | Applicant(s) PICKAR ET AL. | |
| | Examiner Layla Soroush | Art Unit 1617 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-76 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-76 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Priority

The Office Action is in response to the Preliminary Amendment filed July 28, 2003. This application claims benefit of 60/398,718 (07/29/2002), 60/398,719 (07/29/2002), 60/398,720 (07/29/2002), 60/402,542 (08/12/2002), 60/433,781 (12/17/2002), 60/433,782 (12/17/2002), and 60/433,785 (12/17/2002). Claims 1-76 are pending.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-6, 11-30, 31-34, 35-53, 54-62, 63-71, 75, drawn to a method of treating a serious psychotic mental illness comprising administering a combination of (i) an alpha2-adrenergic receptor antagonist and (ii) an atypical antipsychotic neuroleptic, classified in class 514, subclass 220.
- II. Claims 7-10 and 76, drawn to a pharmaceutical composition (i) an alpha2-adrenergic receptor antagonist, (ii) an atypical antipsychotic neuroleptic, and (iii) a pharmaceutically acceptable carrier, classified in class 514, subclass 220.
- III. Claims 72-74, drawn to a method of identifying compounds that are useful to treat serious psychotic mental illness, classified in class 514, subclass 220.

The inventions are distinct, each from the other because of the following reasons:

Inventions II and I are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, a method of treating a serious psychotic mental illness, e.g. neurological and psychotic symptoms in Alzheimer's diseases, Huntington's chorea, Pick's diseases and senile dyskinesia, can be treated with a different product, e.g., an acetylcholinesterase inhibitor such as physostigmine, a precursor of acetylcholine such as choline and lecithin, or an acetylcholine receptor agonist such as arcelone.

Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II, restriction for examination purposes as indicated is proper. The searches in non-patent literature databases are extensive and do not overlap thus presenting a search burden to be searched together. In searching Group II, Examiner will be focusing on the patentability of the composition itself, and not the method of treating a serious psychotic mental illness of Group I. Conversely, in searching Group II, Examiner will be focusing on the patentability of the method of treating a serious psychotic mental illness and not the composition itself. Thus, Groups I and II have been appropriately restricted on the basis of being independent or distinct and presenting a search burden on the Examiner if they were to be searched together.

Inventions III and I-II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are unrelated because Group III is directed to a method of identifying compounds that are useful to treat serious psychotic mental illness, whereas Group I-II is directed to a method of treating a serious psychotic mental illness and the composition. Thus, the methods have different functions and effects. The inventions are also not disclosed as capable of use together, because the steps involved in the method of treating a serious psychotic mental illness and the process of identifying compounds that are useful to treat serious psychotic mental illness are different and are not taught as being equivalent.

Because these inventions are distinct for the reasons given, restriction for examination purposes as indicated is proper. It is noted that while the searches of Groups III and I-II may be overlapping, there is no reason to believe that the searches are co-extensive. In searching Group III, the Examiner will be focusing on the patentability of the process of identifying compounds that are useful to treat serious psychotic mental illness, and not the method of treating a serious psychotic mental illness or the composition of Groups I-II. Conversely, in searching Group I-II, the Examiner will be focusing on the patentability of the method of treating a serious psychotic mental illness and the composition; and not the process of identifying

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compounds that are useful to treat serious psychotic mental illness. Accordingly, a search for both groups would pose an undue burden on the Office.

Election of Species

When applicant elects any of the Groups, an election of species is required. This application contains claims directed to the following patentably distinct species of the claimed invention:

Group I:

a plurality of (i) alpha2-adrenergic receptor antagonists and (ii) atypical antipsychotic neuroleptics (compounds having combined D2 dopamine and 5HT2 serotonin antagonist activities); and a plurality of disclosed patentably distinct conditions or diseases to be treated.

a plurality of (i) compounds that blocks or down-regulates D2 dopamine and 5HT2 serotonin activities and (ii) compounds that blocks or down-regulates alpha2-adrenergic receptor activity; and a plurality of disclosed patentably distinct conditions or diseases to be treated.

a plurality of (i) atypical antipsychotics and (ii) compounds which enhances noradrenergic synaptic activity; and a plurality of disclosed patentably distinct conditions or diseases to be treated.

Group II:

a plurality of (i) alpha2-adrenergic receptor antagonists and (ii) atypical antipsychotic neuroleptics (compounds having combined D2 dopamine and 5HT2 serotonin antagonist activities);

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Claims of Group I reads on methods of treatment of (i) alpha2-adrenergic receptor antagonists and (ii) atypical antipsychotic neuroleptics (compounds having combined D2 dopamine and 5HT2 serotonin antagonist activities); (i) compounds that blocks or down-regulates D2 dopamine and 5HT2 serotonin activities and (ii) compounds that blocks or down-regulates alpha2-adrenergic receptor activity; (i) atypical antipsychotics and (ii) compounds which enhances noradrenergic synaptic activity; and diseases or conditions to be treated, the search for all of which presents an undue burden on the Office.

If applicant chooses an (i) alpha2-adrenergic receptor antagonists and (ii) atypical antipsychotic neuroleptics (compounds having combined D2 dopamine and 5HT2 serotonin antagonist activities) to be examined on the merits; Applicant is required to further elect a single species of an (i) alpha2-adrenergic receptor antagonists and a single species of (ii) atypical antipsychotic neuroleptics (compounds having combined D2 dopamine and 5HT2 serotonin antagonist activities). If applicant chooses the (i) compounds that blocks or down-regulates D2 dopamine and 5HT2 serotonin activities and (ii) compounds that blocks or down-regulates alpha2-adrenergic receptor activity to

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be examined on the merits; Applicant is required to further elect a single species of a (i) compound that blocks or down-regulates D2 dopamine and 5HT2 serotonin activities and a single species of a (ii) compound that blocks or down-regulates alpha2-adrenergic receptor activity. If applicant chooses an (i) atypical antipsychotics and (ii) compounds which enhances noradrenergic synaptic activity to be examined on the merits; Applicant is required to further elect a single species of an (i) atypical antipsychotics and a single species of a (ii) compound which enhances noradrenergic synaptic activity.

Claims of Group II read on a composition with unspecified (i) alpha2-adrenergic receptor antagonists and (ii) atypical antipsychotic neuroleptics, the search for all of which presents an undue burden on the Office.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Notice of Possible Rejoinder

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims

and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Election

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

A telephone call to the attorney is not required where: 1) the restriction requirement is complex, 2) the application is being prosecuted pro se, or 3) the


examiner knows from past experience that a telephone election will not be made (MPEP 812.01). Since the restriction election is considered complex, a call to the attorney for a telephone election was not made.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Layla Soroush whose telephone number is (571)272-5008. The examiner can normally be reached on Monday through Friday from 8:30 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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